UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
EASTERN DIVISION

MAXINE TAYLOR, SHEILAH STEWART, TIFFANY SPANN, NATALIE WASHINGTON, LASHUNDA ROBINSON, ARETHA SHEEHY, EVELYN PIPPIN, LATANYA ARMSTRONG, CHRISTINE DUCK, TARA GRIFFIN JOHNSON, LA'KISHA WYATT NASH, ANGELA MOORE — PLAINTIFFS

VS. — CIVIL ACTION NO. 4:03CV148LN

PHARMACIA-UPJOHN COMPANY, LLC. — DEFENDANT

MEMORANDUM OPINION AND ORDER

This cause is before the court on cross-motions for summary judgment filed by defendant Pharmacia-Upjohn Company, LLC (Pharmacia) and plaintiffs Maxine Taylor, Sheilah Stewart, Tiffany Spann, Natalie Washington, Lashunda Robinson, Aretha Sheehy, Evelyn Pippin, Latanya Armstrong, Christine Duck, Tara Griffin Johnso, La'Kisha Wyatt Nash and Angela Moore. The parties have responded to the others' motion(s), and the court, having considered the memoranda of authorities, together with attachments, submitted by the parties, concludes that plaintiffs' motion should be denied and defendant's motions granted.

Plaintiffs filed this suit on November 18, 2002 seeking to recover damages for personal injuries allegedly sustained as a result of using the Depo-Provera Contraceptive Injection (DPCI), an injectable contraceptive manufactured and marketed by Pharmacia

& Upjohn (P&U).[1] Plaintiffs all allege that they suffered a combination of various adverse effects from their use of this drug, typically including, but not limited to, weight gain/obesity, headaches, menstrual irregularities, hypertension and depression, and also that as a result of their use of the drug, they are at increased risk for breast and cervical cancer and various obesity-related illnesses.

On September 30, 2005, the deadline established by the case management order for filing dispositive motions, both plaintiffs and defendant filed motions for summary judgment. Plaintiffs also contemporaneously moved to amend their complaint alleging a "newly discovered" injury of bone mineral density (BMD) loss. By order dated November 18, the magistrate judge denied plaintiffs' motion for leave to amend, and thus plaintiffs have no claim in this action for personal injury in the form of loss of BMD from using DPCI. However, plaintiffs' motion for summary judgment was filed prior to the denial of plaintiffs' request to amend and seeks judgment based in part on arguments and evidence relating to a putative claim for loss of BMD. Such evidence is not pertinent and will be disregarded.

In support of their motion for summary judgment, plaintiffs point to the reports prepared by their medical expert, Dr. Calvin

[1] Plaintiffs filed the suit in the Circuit Court of Noxubee County, Mississippi, but it was subsequently removed by defendant on the basis of diversity of citizenship.

Ramsey, in which he opines in the case of all but one plaintiff that certain of the maladies of which plaintiffs complain were proximately caused and/or accelerated by their use of DPCI.[2] In addition to this, they identify both an excerpt from the 2002 Physician's Desk Reference, which listed some of the dangers posed by DPCI as including many of the adverse side effects claimed to have been suffered by these plaintiffs, and they also highlight a special "black box" warning issued by defendant in November 2004, which warned of the danger of the loss of significant BMD which was "greater with increasing duration of use and may not be completely irreversible."[3] Plaintiffs assert that they were never

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[2] The court notes at the outset that in the case of Lashundra Robinson, Dr. Ramsey's expert report recites that after reviewing her medical records,

> *I cannot at this time find to a reasonable degree of medical probability a causative relationship between Ms. Robinson's use of Depo Provera, her weight gain, menstrual irregularities and nervousness*. . . . While Depo-Provera has been associated with an increased risk of developing cancer of the breasts and cervix, critical gynecological data is absent from the record to draw valid conclusions. Obesity is a risk factor for several diseases, including hypertension, type II diabetes mellitus, hyperlipidemia, coronary artery disease, sleep apnea, stroke, liver disease, muscoluskeletal disease, colon cancer, & endometrial cancer. The association is not strong enough at this time to assign a causative relationship.

In view of Dr. Ramsey's inability to establish a causal relationship between DPCI and Ms. Robinson's claimed injuries, this plaintiff's claim obviously fails.

[3] At that time, the company warned that in view of the potential loss of BMD with prolonged use, "[DPCI] should be used as a long-term birth control method (eg. longer than 2 years) only if other birth control methods are inadequate." The court would

informed of the true risks and dangers of using DPCI, and thus declare that they

> should be compensated both for those damages concerning loss of BMD, bone mineral density, as well as the litany of dangers posed for those women who have taken [DPCI] and suffered every other thing from hypertension, and depression. To cancer of the breast and cervix, to those who have suffered increased risks of strokes, and heart attacks[, a]s well as increased risk of osteoporotic fractures both early on and later in life.

In response to plaintiffs' motion, and in support of its own summary judgment motions, defendant contends that it is entitled to summary judgment on all plaintiffs' claims because they lack competent, admissible expert testimony to support their allegations that they have suffered harm as a result of using DPCI and because defendant, in keeping with its duty under the law, provided plaintiffs' healthcare providers with adequate warnings of all known risks associated with the use of DPCI. Defendant submits, in addition, that many of the plaintiffs' claims are time-barred. For the reasons that follow, defendant is entitled to summary judgment and plaintiff is not.

All of the plaintiffs herein assert that as a result of their use of DPCI, they are at an increased risk of breast and cervical

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reiterate, though, that evidence pertinent to the potential for loss of BMD from using DPCI is not at issue in the case and is not considered in assessing whether summary judgment is in order for either party.

cancer, and all claim to have suffered one or more adverse effects from their use of DPCI.

Regarding their claims for damages on account of allegedly having an increased risk of breast cancer and cervical cancer from using DPCI, the court would first note that there is no proof in the record that any plaintiff has been diagnosed with breast cancer or cervical cancer. However, plaintiffs' proffered expert, Dr. Calvin Ramsey, states the following in his report on each plaintiff (with the exception of Ms. Robinson, discussed supra note 2):

> Previous administration of Depo-Provera in all probability exposed her to an increased risk of developing cancer of the breasts and cervix. While data is inconclusive on other organs, this increased risk is unacceptable given the alternatives for birth control at the time she used Depo-Provera.

In those plaintiffs who reported a family history of cancer, Dr. Ramsey added the lead-in phrase, "Because she has a strong family history of cancer, previous administration of . . . ." Defendant submits that under Mississippi law, recovery for a future illness must "await a manifestation of that illness or be supported by . . . medical or scientific evidence. . . ." Leaf River v. Ferguson, 662 So. 2d 648, 650 (Miss. 1995). It contends that since no plaintiff has any physical manifestation of cancer, none has any cognizable claim for increased risk of cancer. It submits additionally that even assuming such a claim might theoretically exist, these plaintiffs have no viable claim inasmuch as there is

no medical or scientific basis for Dr. Ramsey's proclamation that Depo-Provera has increased these plaintiffs' risk of breast and cervical cancer. It contends, finally, that the package inserts accompanying Depo-Provera disclosed any possible risk of cancer associated with the use of DPCI, so that its duty to warn was fully discharged.

The Mississippi Supreme Court recognized in Ferguson that a claim for fear of developing cancer may lie if the plaintiff is able to prove substantial exposure to a product that is a known carcinogen so that there is a basis for that fear. See Ferguson, 662 So. 2d at 650 ("We do not harm and, in fact, preserve a recovery for emotional distress when the same is based on" proof of "substantial exposure to the danger, and . . . medical or scientific evidence [providing] a rational basis for the emotional fear."). What is lacking, though, is proof of "medical or scientific evidence" from the plaintiffs suggesting a basis for finding that these plaintiffs are, in fact, at an appreciably increased risk for developing breast or cervical cancer. The court does realize that Dr. Ramsey has declared this to be so. However, in the exercise of its gate-keeping function, the court must view his testimony in this regard as unreliable, as there is lacking in the record any evidence suggesting any medical or scientific basis for Dr. Ramsey's opinion other than his statement that it is so; and this, of course, is patently insufficient to

support admission of his testimony. See McNabney v. Laboratory Corp. of America, 2005 WL 2997969, *1 (5th Cir. 2005) (reiterating the principle that it is not so merely because an expert says it is so, and concluding that a medical causation expert's testimony which did not consider and exclude other possible causes of injury was not admissible); Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998) (stating that "a scientific opinion, to have evidentiary relevance and reliability, must be based on scientifically valid principles"); Joiner v. General Elec. Co., 78 F.3d 524, 519 (11th Cir. 1996) (stating that "nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); Knight v. Armstrong Rubber Co., 1991 WL 532493 (S.D. Miss. 1991) (mere conclusory, unsubstantiated opinions do not render an opinion admissible). Here, there is no data whatsoever offered in support of Dr. Ramsey's conclusion. All that is offered is his conclusion. Accordingly, plaintiffs cannot succeed in their effort to recover for any alleged increased risk of breast and cervical cancer from their use of DPCI. See McNabney, 2005 WL 2997969, at *2 (holding that where the expert testimony of plaintiff's medical causation experts could not be considered, the plaintiff "was unable to prove

causation, an essential element of her negligence claim, and that summary judgment was therefore proper).

As an additional basis in support of its motion for summary judgment on this claim, defendant argues that the package insert for DPCI properly and adequately warned of the risks of cancer associated with DPCI. DPCI is available only upon the prescription of a licensed physician. The law requires that every prescription drug include a package insert, approved by the Food and Drug Administration (FDA), listing known side effects, and communicating to prescribing physicians the essential information about the medication's benefits and risks. See 21 C.F.R. §§ 201.56-201.57 (2002). "Under Mississippi law, [t]he general rule is 'that where prescription drugs are concerned, a manufacturer's duty to warn only extends to physicians and not to laymen.'" Janssen Pharmaceutica, Inc. v. Bailey, 878 So. 2d 31, 57 (Miss. 2004) (quoting Swayze v. McNeil Labs., Inc., 807 F.2d 464 (5th Cir. 1987)). Thus, defendant had no duty to directly warn these plaintiffs of known adverse side effects associated with the use of DPCI, but rather had only the duty to adequately warn plaintiffs' physicians of any known adverse effects associated with use of the drug. Wyeth Laboratories, Inc. v. Fortenberry, 530 So. 2d 688, 691 (Miss. 1988) (citing Swayze).

Although the "issue of a warning's adequacy is factual and usually will be resolved by the trier of fact," Wyeth, 530 So. 2d

at 692, this issue, like any other factual matter, may be susceptible to a determination by the court as a matter of law if the facts are not in controversy and no reasonable fact-finder could find that the warnings provided were other than adequate, see id. (finding warnings in package insert adequate as a matter of law). That is the case here.

The record herein reflects that the FDA-approved package insert for DPCI[4] during all relevant time periods provided the following information:

> **WARNINGS**
>
> *4. Cancer Risks*
>
> Long-term case-controlled surveillance of users of [DPCI] . . . found slight or no increased overall risk of breast cancer and no overall risk of ovarian, liver, or cervical cancer and a prolonged, protective effect of reducing the risk of endometrial cancer in the population of users.
>
> An increased relative risk (RR) of 2.19 (95%CI 1.23 ro 3.89) of breast cancer has been associated with use of [DPCI] in women whose first exposure to the drug was within previous 4 years and who were under 35 years of age [CI-Confidence Interval]. However, the overall RR for ever-users of [DPCI] was only 1.2% (95% CI 0.96 to 1.52). . . .
>
> A statistically insignificant increase in RR estimates of invasive squamous-cell cervical cancer has been associated with the use of [DPCI] in women who were first exposed before the age of 35 years (RR 1.2 to 1.28 and 95% CI 0.93 to 1.70). The overall, nonsignificant relative rate of invasive squamous-cell cervical cancer in women who ever used [DPCI] was estimated to be 1.11 (95% CI 0.96 to 1.29). No trends in risk with duration

[4] It is undisputed that DPCI was approved by the Food and Drug Administration for non-contraceptive gynecologic indications in 1960 and has been continuously approved in the United States since that time for gynecologic and oncologic indications.

> of use or times since initial or most recent exposure were observed.

Plaintiffs have offered no evidence that this warning failed to accurately portray the cancer risk associated with use of DPCI or that the warning as given was other than adequate.

The plaintiffs do allege in their complaint that no one ever told them about any risks of using DPCI; but again, the manufacturer's duty is only to warn physicians, not to warn the patients themselves. It is the physician's responsibility to inform the patient and to secure her informed consent, and a failure in that regard is not a basis for imposing liability against the manufacturer, which fulfilled its duty by appropriately informing the physician.

As regards plaintiffs' claims for injuries claimed to have been suffered from using DPCI, the only expert testimony offered by plaintiffs in support of their claims is that of Dr. Ramsey; and, whereas most of the plaintiffs claim to have experienced numerous adverse effects from their use of DPCI, Dr. Ramsey's opinion provides no support for most of these claims. This can readily be seen by comparing the conditions alleged by each plaintiff to the conditions alleged by each plaintiff which Dr. Ramsey has opined can be causally linked to her use of DPCI:

Plaintiff's Claimed Condition	Dr. Ramsey's Causation Opinion
Armstrong: weight gain and menstrual irregularities	weight gain menstrual irregularities

Duck: abdominal pain, ear aches, skin rashes, scaly skin, boils, amenorrhea, weight gain, chills, fever and arthritis	weight gain
Griffin: hair loss, weight gain, stomach pains, difficulty conceiving, two miscarriages and headaches	weight gain and hypertension[5]
Moore: heavy bleeding, hair loss and weight gain	weight gain
Nash: unspecified personal injuries	weight gain, headaches, menstrual irregularities and depression
Pippen: irregular menstrual bleeding, weight gain and hypertension	weight gain and hypertension
Robinson: unspecified personal injuries	none
Sheehy: hair loss, weight gain, hypertension, nervousness, a miscarriage, abnormal pap smears and pain and swelling at the injection site	weight gain and hypertension
Spann: weight gain, high blood pressure nausea, headaches, fatigue, nose bleeds, dizziness, stomach cramps, irregular bleeding, swelling, memory loss, and increased appetite	weight gain

[5] Although Griffin does not complain of hypertension, Dr. Ramsey's opinion indicates that hypertension was caused by DPCI.

Stewart: depression, headaches, atypical cells and hair loss	weight gain, headaches, menstrual irregularities and nervousness[6]
Taylor: headaches, loss of appetite, weight loss, miscarriages, swelling of fingers and hands, loss of memory, irritation of the skin, abnormal menstrual cycles, loss of sleep, dimmed vision and upset stomach	weight gain and hypertension[7]
Washington: weight gain and a pulmonary embolism	weight gain and pulmonary emboli

A plaintiff cannot recover for any condition for which she has no expert medical testimony to substantiate a causal link between the allegedly offending product and the condition. See McNabney, 2005 WL 2997969, at *1. It obviously follows, then, that no plaintiff can recover for any condition that Dr. Ramsey has not opined to have been caused by her use of DPCI.

There are few conditions which Dr. Ramsey has opined were caused by the use of DPCI in the case of one or more plaintiffs, including weight gain, hypertension, menstrual irregularities, headaches, nervousness, and depression. However, the package

[6] Although Stewart does not complain of weight gain, menstrual irregularities or nervousness, Dr. Ramsey has opined that such conditions were caused by her use of DPCI.

[7] Although Taylor does not complain of hypertension, Dr. Ramsey has opined that such conditions were caused by her use of DPCI.

insert included warnings as to many of these conditions as potential side effects of DPCI, stating as follows:

> **WARNINGS**
>
> *1. Bleeding Irregularities*
>
> Most women using [DPCI] experience disruption in bleeding patterns. Altered menstrual bleeding patterns include irregular or unpredictable bleeding or spotting, or rarely, heavy or continuous bleeding. If abnormal bleeding persists and is severe, appropriate investigation should be instituted to rule out the possibility of organic pathology, and appropriate treatment should be instituted when necessary.
>
> As women continue using [DPCI], fewer experience intermenstrual bleeding and more experience amenorrhea. By month 12 amenorrhea was reported by 55% of women, and by month 24 amenorrhea was reported by 68% of women using [DPCI].
>
> . . .
> **PRECAUTIONS**
>
> GENERAL
> . . .
> ***3.*** *Weight Changes*
> There is a tendency for women to gain weight while on therapy with [DPCI]. From an initial average body weight of 136 lb. Women who completed 1 year of therapy with [DPCI] gained an average of 5.4 lb. Women who completed two years of therapy gained an average of 8.1 lb.
>
> Women who completed four years gained an average of 13.8 lb. Women who completed 6 years gained an average of 16.5 lb. Two percent of women withdrew from a large-scale clinical trial because of excessive weight gain.

The Package Insert further stated, in the "Adverse Reactions" section, as follows:

> In the largest clinical trial with [DPCI], over 3,000 women, who were treated for up to 7 years,

> reported the following adverse reactions, which may or may not have been related to the use of [DPCI].
>
> The following adverse reactions were reported by more than 5% of subjects: Menstrual irregularities (bleeding or amenorrhea, or both). . . Weight changes, headaches, nervousness, Abdominal Pain or discomfort. . . Dizziness . . . Asthenia (weakness or fatigue).

The package insert thus clearly apprised physicians of the possibility of weight gain, menstrual irregularities, nervousness, and headaches associated with use of DPCI,[8] and defendant thus discharged its duty to warn. See Janssen, 878 So. 2d at 57. Defendant cannot be held liable merely because plaintiffs' physicians may not in turn have imparted this information to the plaintiffs.[9]

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[8] Notably, plaintiffs have offered no evidence challenging the adequacy of the warnings included in the package insert.

[9] Although plaintiffs allege in the complaint that they were never informed by anyone of any risks associated with using DPCI, defendant points out in its motions as to the claims of Armstrong, Griffin, Nash, Pippin and Sheehy that each of these plaintiffs actually signed "consent" forms prepared by the Mississippi Department of Health indicating that they had been specifically advised of the benefits, risks and potential side effects of risks and benefits of using DPCI, including the slight increased risk of breast cancer for women age 30 to 35, and potential side effects of altered menstrual periods, weight gain, fluid retention, fatigue, nervousness, headaches and dizziness. These plaintiffs have offered no contradictory proof, and Pippin in fact admitted in her deposition that she was aware of the specific risks of which she complains herein.

Defendant further points out that a number of the plaintiffs (including Armstrong, Spann and Stewart actually resumed DPCI injections after this lawsuit was filed, a fact which under any view would undermine their (implicit) allegation that they would not have chosen DPCI as a form of contraception had they been fully informed of the risks.

The package inserts do not indicate depression or hypertension as possible adverse side effects of using DPCI. However, plaintiff has offered no competent, admissible expert testimony that either of these conditions is a known side effect of DPCI, or that such conditions in these individuals was caused by DPCI. Again, there is no evidence of any medical or scientific data supporting Dr. Ramsey's conclusion in this regard.[10] Accordingly, the claims by the plaintiffs who seek recovery for either or both of these alleged injuries fail for that reason.

Given the absence of admissible expert testimony supporting plaintiffs' claim for alleged increased risk of breast and cervical cancer, and for numerous other conditions which they claim to have suffered as a result of using DPCI, and given the fact that defendant provided warnings to physicians via its package inserts as to known adverse risks of using DPCI, defendant is entitled to summary judgment.[11]

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[10] In addition to this shortcoming in his testimony, defendant has demonstrated, without contradiction, that Dr. Ramsey's opinions in the cases of many, if not most, of the plaintiffs is based on gross factual inaccuracies. It would serve no useful purpose to catalogue those inaccuracies, as defendant has done an adequate job of this in its memoranda. It must be said, however, that these glaring errors in his reports are conclusive evidence of the unreliability and illegitimacy of his opinions.

[11] Defendant's argument that certain of the plaintiffs' claims are barred by the statute of limitations need not be addressed in view of the court's conclusion that summary judgment is in order on other grounds, though the court would note that defendant's limitations arguments do appear meritorious.

Based on the foregoing, it is ordered that defendant's motion for summary judgment is granted.

A separate judgment will be entered in accordance with Rule 58 of the Federal Rules of Civil Procedure.

SO ORDERED this 19th day of December, 2005.

/s/ Tom S. Lee
UNITED STATES DISTRICT JUDGE